NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD et al., Defendants.	**Civil Action No. 22-4248 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for partial judgment on the pleadings, pursuant to Federal Rule of Civil Procedure 12(c), by Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC (collectively, "Bausch.") Defendants Padagis Israel Pharmaceuticals LTD, Padagis LLC, and Padagis US LLC (collectively, "Padagis") have opposed the motion. Bausch seeks partial judgment on the pleadings on the inequitable conduct affirmative defenses (Second Affirmative Defense as to "enforceability" and Sixth Affirmative Defense) and counterclaim (Third Counterclaim) asserted by Padagis. For the reasons that follow, the motion will be granted.

This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Bausch, which owns U.S. Patent No. 11,311,482 (the "'482 Patent") covering its Arazlo® pharmaceutical product, and Padagis, which has filed ANDA No. 215393, seeking to

make and sell a generic version of Arazlo®. The following facts are undisputed. The Padagis ANDA contains a paragraph IV certification that the proposed product will not infringe any valid claim of the '482 patent. After Padagis sent Bausch the required notice letter, Bausch filed the instant suit. The Complaint asserts a claim for patent infringement of the '482 patent. On May 9, 2023, Padagis filed an Amended Answer to the Complaint asserting, *inter alia*, an affirmative defense of inequitable conduct and a counterclaim seeking a declaration of unenforceability of the '482 patent due to inequitable conduct.

The Amended Answer alleges the following facts about the relevant prosecution history. In short, during prosecution, the Examiner rejected a group of claims as obvious over Dow in view of Donello. (Am. Answer ¶¶ 31-35.) The Amended Answer alleges:

> 31. On October 28, 2019, the Examiner mailed a Final Office Action, rejecting pending claims 13-40 as obvious over WO 2016/205001 ("WO '001" or "Dow") in view of U.S. Publication 2012/0328670 ("Donello"). *See* Ex. 4, October 28, 2019 Final Office Action at 3. The Examiner noted that WO '001 teaches lotions containing halobetasol and tazarotene, wherein the tazarotene is present in concentrations of less than 0.5%, in an oil-in-water emulsion. *See id.* at 4-5. The Examiner noted that WO '001 even teaches the amounts disclosed in pending claim 40. *See id.* at 6. The Examiner acknowledged that WO '001 does not teach treatment for acne, and relied on Donello, which teaches a tazarotenic acid composition for the treatment of skin disorders such as acne vulgaris. *See id.* at 6-7. The Examiner found that "It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow. One would have been motivated to employ tazarotenic acid because it is known that topically administered tazarotenic acid is effective in the treatment of skin disorders (e.g. psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary." *Id.* at 7.

The Amended Answer alleges that the applicants subsequently amended independent claim 1 to make tazarotene .045% the sole active ingredient. (Am. Answer at ¶ 36.) The Amended Answer states that the PTO responded with a notice of allowance:

> 37. On January 04, 2022, the Examiner issued a notice of allowance, stating that "Applicants amendment of claims to recite tazarotene as a sole active agent renders the obviousness rejection moot. Because Dow teaches that tazarotene and halobetasol is synergistic[] and there is no motivation to administer tazarotene alone in view of Dow."

The Amended Answer alleges that the applicants withheld certain spreadsheets, which showed use of tazarotene .05% to treat acne. (Am. Answer ¶ 45.) The Amended Answer asserts:

> But-for Dr. Pillai's failure to disclose information regarding the off-label prescriptions of 0.05% Tazorac® for the treatment of acne that occurred prior to the earliest effective-filing date of the '482 patent, the claims of the '482 patent would not have been allowed.

(Am. Answer ¶ 46.) Defendant's inequitable conduct counterclaim relies on these factual assertions.

In Therasense, the Federal Circuit set forth the "but for" materiality standard for claims of inequitable conduct:

> This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011)

In pleading the inequitable conduct counterclaim, the Amended Answer asserts that the withheld spreadsheets meet the but-for materiality standard:

> 45. Information regarding the off-label prescriptions of 0.05% Tazorac® for the treatment of acne that occurred prior to the earliest effective-filing date of the '482 patent would have been material to the patentability of the pending claims of the application that resulted in the '482 patent. The claims of the '482 patent recite, *inter alia*, a method of treating acne through topical application of a composition comprising tazarotene as the sole active ingredient at a concentration of "about

> 0.045%." *See* Ex. 1 at claim 1. According to the information provided to Dr. Pillai on March 25, 2015, there were more than one million prescriptions for topical compositions comprising tazarotene as the sole active ingredient at a concentration of 0.05% (i.e., "about 0.045%") for the treatment of acne in the U.S. over a four-year period from 2010 to 2014. Such information directly contradicts Applicant's arguments to the PTO throughout prosecution of the '482 patent that a person of ordinary skill in the art would not have been motivated with a reasonable expectation of success to lower the concentration of tazarotene to a concentration of about 0.045%. *See, e.g.,* Ex. 5 January 28, 2020 Response to Final Office Action at 11.
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> 46. But-for Dr. Pillai's failure to disclose information regarding the off-label prescriptions of 0.05% Tazorac® for the treatment of acne that occurred prior to the earliest effective-filing date of the '482 patent, the claims of the '482 patent would not have been allowed. For example, the Examiner emphasized in the Notice of Allowance that "amendment of claims to recite tazarotene as a sole active agent renders the obviousness rejection moot [b]ecause Dow teaches that tazarotene and halobetasol is synergistic[] and there is no motivation to administer tazarotene alone in view of Dow." *See* Ex. 11, January 04, 2022 Notice of Allowance. However, the Examiner was not made aware of the significant off-label prescriptions of 0.05% Tazorac® for the treatment of acne that occurred prior to the earliest effective-filing date of the '482 patent, which constitute prior art public use of topical compositions with tazarotene as the sole active ingredient at a concentration of "about 0.045%" for treating acne.

(Am. Answer at ¶¶ 45-46.) In short, paragraph 45 alleges that disclosure of the spreadsheets would have undercut the applicants' contention that a POSA "would not have been motivated with a reasonable expectation of success to lower the concentration of tazarotene to a concentration of about 0.045%." Paragraph 46 points to a statement in the Notice of Allowance about overcoming a rejection due to obviousness in view of Dow, and suggests that, but for the withholding of the spreadsheets, the applicants would not have overcome this rejection and obtained allowance.

Bausch moves for partial judgment on the pleadings as to the affirmative defenses and the counterclaim related to inequitable conduct. The Third Circuit has stated:

> We analyze a motion for judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) under the same standards that apply to a Rule 12(b)(6) motion. Under Rule 12(c), a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party. A court may grant a Rule 12(c) motion if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law. A plaintiff can survive a Rule 12(c) motion if her complaint contains sufficient factual matter to show that the claim is facially plausible, thus enabling the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.

Bibbs v. Trans Union LLC, 43 F.4th 331, 339 (3d Cir. 2022) (citations omitted.)

Bausch argues: "Padagis's inequitable conduct claim suffers a simple, uncorrectable deficiency: it fails to identify material subject matter not already disclosed during prosecution." (Pl.'s Br. at 13-14.) Plaintiff moves for partial judgment on the pleadings, arguing, in short, that the applicants otherwise disclosed the prior art use of .05% tazarotene for the treatment of acne, and that the spreadsheets in question are merely cumulative of these other prior art disclosures. Plaintiff cites Dig. Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1319 (Fed. Cir. 2006): "a withheld otherwise material prior art reference is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner;" Regeneron Pharm., Inc. v. Merus N.V., 864 F.3d 1343, 1350 (Fed. Cir. 2017) ("A reference is not but-for material, however, if it is merely cumulative.") Plaintiff contends that the spreadsheets are cumulative of two references that were before the examiner, Shalita 1999 and Kircik 2009,[1] both of which, Plaintiff states, disclose the use of .05% tazarotene to treat acne.

[1] Both references appear in the list of non-patent citations in the '482 patent.

Crucially, in opposition, Defendant agrees that the Shalita and Kircik references are clinical studies of the use of, *inter alia*, .05% tazarotene to treat acne. (Def.'s Opp. Br. at 15.) Nonetheless, Defendant argues that the spreadsheets are not cumulative of Shalita and Kircik because the spreadsheets document this use in "real-world clinical practice" rather than "experimental clinical studies." (Id. at 16.) Defendant contends:

> While Kircik and Shalita suggest the use of 0.05% tazarotene to treat acne, the withheld spreadsheets show that clinicians were absolutely motivated to use 0.05% tazarotene to treat acne and, in fact, were actually doing so on a regular basis.

(Def.'s Opp. Br. at 16.) Defendant's opposition relies entirely on this alleged distinction. The problem for Defendant is that this is a new argument unsupported by the factual allegations in the Amended Answer. The Third Counterclaim, as pled in the Amended Answer, says nothing about real-world clinical practice, nor about the distinction between use of a treatment in a study versus use in clinical practice. No facts have been pled which would make plausible the inference that, but for the withholding of the spreadsheets, the applicants would not have overcome the rejection for obviousness in view of Dow and Donello, and obtained allowance.

Defendant did not dispute that, on this motion, the Court may consider references listed on the face of the patent and included in the file wrapper. Defendant does, however, argue that the matter of whether or not the spreadsheets are cumulative of the Kircik and Shalita references is a factual determination that cannot be resolved at the pleading stage. The Court is not persuaded, as the issue presently before the Court is not an ultimate fact, but rather the sufficiency of the pleadings to make plausible an inference of materiality. Defendant has not challenged Plaintiff's representation of the teachings of the Shalita 1999 and Kircik 2009 references. Defendant has instead opposed Plaintiff's argument by alleging a difference

between the spreadsheets and Shalita and Kircik – the use in clinical practice as opposed to research. Defendant has not provided any factual basis to make plausible the inference that, but for the withholding of this evidence of use in clinical practice rather than research, the applicants would not have obtained allowance. The Third Counterclaim fails to plead sufficient facts to make plausible the inference of materiality, as required by Therasense. Plaintiff has clearly established that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law. Plaintiff is entitled to partial judgment on the pleadings, and the motion will be granted. Defendant's third counterclaim of inequitable conduct and its affirmative defenses of inequitable conduct[2] will be dismissed.

Plaintiff asks this Court to dismiss the Third Counterclaim, but does not address the question of whether it seeks a dismissal with or without prejudice. The Supreme Court has characterized dismissal with prejudice as a "harsh remedy." New York v. Hill, 528 U.S. 110, 118 (2000). Dismissal of a count in a complaint with prejudice is appropriate if amendment would be inequitable or futile. "When a plaintiff does not seek leave to amend a deficient complaint after a defendant moves to dismiss it, the court must inform the plaintiff that he has leave to amend within a set period of time, unless amendment would be inequitable or futile." Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002); see also Connelly v. Steel Valley Sch. Dist., 706 F.3d 209, 217 (3d Cir. 2013) ("It does not matter whether or not a plaintiff seeks leave to amend.") Thus, this Court must address the question of whether Defendant will

[2] The Sixth affirmative defense targets the issue of unenforceability due to inequitable conduct. The Second affirmative defense generally references defenses to patent enforceability; to the limited extent that the Second affirmative defense includes unenforceability due to inequitable conduct, it will be dismissed.

be granted leave to amend the third counterclaim. The Court observes that Defendant has not suggested that repleading might remedy the deficiency that has led to dismissal. Defendant's opposition did not, in fact, suggest any way that its theory about the spreadsheets, as evidence of clinical practice rather than research use, can be made viable. The Court concludes that amendment is futile, and the Third Counterclaim will be dismissed with prejudice.

For these reasons,

IT IS on this 30th day of October, 2023

ORDERED that Plaintiff's motion for partial judgment on the pleadings (Docket Entry No. 73) is **GRANTED**; and it is further

ORDERED that Defendant's inequitable conduct affirmative defenses (the Second Affirmative Defense to the extent that it covers "enforceability" due to inequitable conduct and the Sixth Affirmative Defense) and Third Counterclaim are hereby **DISMISSED** with prejudice.

/s Stanley R. Chesler
STANLEY R. CHESLER. U.S.D.J.